TITLE: Research Involving Vulnerable Populations and Other Special Categories of Participants

1.0 PURPOSE

The purpose of this policy is to describe the requirements for investigators to submit projects to the VA Central IRB that involve research with vulnerable populations and other special categories of research participants that may need additional safeguards. It also establishes the requirements the VA Central IRB will use in reviewing and approving research involving these populations.

2.0 REVISION HISTORY

Date of Initial Approval	July 18, 2008
Prior Revision Dates	April 20, 2009 September 24, 2009 March 22, 2010

3.0 SCOPE

This policy applies to all VA Central IRB support staff, VA Central IRB members, investigators, and all project team members involved in research reviewed and approved by the VA Central IRB in which members of these vulnerable populations are participants.

4.0 POLICY

4.1 It is the policy of the VA Central IRB that all projects it reviews involving vulnerable populations and other special classes of participants meet all VA and other requirements for such review, and that additional protections and safeguards are considered for these populations as necessary to ensure that the principles of respect for persons, beneficence, and justice as detailed in the *Belmont Report* are met. The VA Central IRB follows the policies on vulnerable populations as set forth in VHA Handbook 1200.05, Appendix D. The VA has not adapted regulations similar to 45 CFR 46 Subparts B through D.

4.2 In accordance with VA and other federal requirements, research participants considered vulnerable include:

- Pregnant women
- Prisoners
- Participants with impaired decision-making capacity
- Children
- Economically and educationally disadvantaged participants

Their involvement in a research project requires that the VA Central IRB make additional determinations to ensure adequate safeguards are included in the project by the investigators to protect the rights and welfare of these populations.

4.3. Other special categories of participants that may be potentially susceptible to undue influence or coercion and may require additional safeguards and protections of their rights and welfare include but are not limited to the following:

- Participants who are illiterate or have limited or no English language proficiency
- Students and employees of the VA, in particular, employees of the project investigators
- Terminally ill participants

4.4 The VA Central IRB will not approve any project in which a fetus, in-utero or ex-utero (including human fetal tissue), is a research subject nor will it approve any research related to *in* vitro fertilization.

4.5 Projects in which some or all of the participants are recruited from vulnerable populations as described in paragraph 4.2 are initially reviewed by the convened VA Central IRB and are not reviewed under expedited review procedures, even if the project otherwise qualifies for expedited review. Populations listed in paragraph 4.3 may be reviewed using the expedited review process upon the discretion of a VA Central IRB Co-Chair.

4.6 It is the policy of the VA Central IRB that no individual, including vulnerable or other special categories of participants, should be prevented from having the opportunity to participate in approved human research unless such a category is otherwise prohibited from participating by VA or other requirements.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 Investigators are responsible for describing in their project application the population from which research participants are to be recruited. If some or all of the participants are recruited from vulnerable or other special categories as described in paragraphs 4.2 and 4.3., the investigator is also required to describe any additional protections and safeguards that are included in the project to protect the rights and welfare of those participants. Investigators are responsible for following all these safeguards during the conduct of the project, as well as any additional safeguards required by the VA Central IRB for project approval.

6.2 The VA Central IRB Administrator and Coordinators are responsible for ensuring that investigators complete and submit all required documentation and/or supplements if their project includes vulnerable populations and/or other special classes

of participants. The VA Central IRB Administrator is also responsible for ensuring that a VA Central IRB member, or an ad hoc advisor who has experience with the defined vulnerable population or other special class of participants included in the project, is in attendance at the convened meeting when the project is reviewed. The VA Central IRB Administrator is responsible for scheduling or conducting specialized IRB training pertaining to specific research projects where vulnerable subjects will be involved.

6.3 VA Central IRB members are responsible for determining whether participants are capable of making an informed and independent choice about whether to participate in the project. If there are groups or individuals who may be subject to coercion or undue influence, or the participants have impaired decision-making capacity, the IRB must evaluate whether there are additional safeguards included in the research project and whether they are sufficient to protect the rights and welfare of the participants. The members will also ensure that the additional protections and safeguards reduce the potential for coercion or undue influence. The IRB Co-Chairs share responsibility for requesting specialized training for the IRB members concerning a certain vulnerable population.

7.0 PROCEDURES

7.1 Receipt of a Project Application Involving a Vulnerable Population or Other Special Class of Participants.

7.1.1 Upon receipt of a project application that involves a vulnerable population as potential participants, the VA Central IRB Coordinator verifies that the investigator included the pertinent supplement (VA Central IRB Form 110 series) for that vulnerable population in the project documentation. This supplement is required if the project involves pregnant women, prisoners, or participants with impaired decision-making capacity, but is not required for children. If it is not included, the investigator is contacted and asked to complete it.

7.1.2 If the project involves a special category of participants that may be potentially vulnerable as defined in paragraph 4.3 a separate vulnerable population supplement is not required. The VA Central IRB Coordinator verifies that safeguards and protections for these populations are included in the applicable portions of the VA Central IRB Form 108, Principal Investigator New Project Application.

7.1.3 When all required documentation is received, the VA Central IRB Coordinator adds the project to the next regularly scheduled VA Central IRB meeting agenda and processes the project for review in accordance with VA Central IRB SOP 108, VA Central IRB Meeting Preparation and Meeting Administration, if the project involves a population listed in paragraph 4.2. If the project involves a population listed in paragraph 4.3, it may be reviewed in accordance with VA Central IRB SOP 110, Expedited Review Process, at the discretion of the VA Central IRB Co-Chair. The Co-Chair will review the VA Central IRB Form 108, Principal Investigator/Study Chair New Project Application, and inform the VA Central IRB Administrator of his/her decision.

The decision will be documented on VA Central IRB Form 109b, Administrative Pre-Screening Checklist for PI/SC New Project Application.

7.1.4 The VA Central IRB Administrator will ensure that a VA Central IRB member, or an ad hoc consultant, who has expertise with the vulnerable population involved in the study will attend the meeting if the study involves one of the following vulnerable populations: pregnant women, prisoners, children, participants with impaired decision-making capacity, and economically and/or educationally disadvantaged participants.

7.2 Research Involving Pregnant Women. For projects involving pregnant women, the investigator must complete VA Central IRB Form 110a, Vulnerable Population Supplement (Pregnant Women) (Enclosure 1) and submit it along with all other project documentation. The VA Central IRB uses this supplement and all the other documentation provided by the investigator to determine whether the additional safeguards included in the project are adequate to protect the participants rights and welfare or whether additional safeguards are required for project approval.

7.2.1 No pregnant women may be involved as a participant in a research project unless at least one of the following conditions is met:

7.2.1.1 The purpose of the activity is to meet the health needs of the mother or the fetus such that the risk to the fetus is minimal, and in all cases is the least possible risk for achieving the objectives of the project.

7.2.1.2 The risk to the fetus presents no more than minimal risk.

7.2.1.3 The mother and father are legally competent and will give their informed consent after being fully informed regarding possible impact on the fetus of the research. The father's informed consent need not be secured if one of the following criteria is met:

- The purpose of the activity is to meet the health needs of the mother
- The father's identity or whereabouts cannot be reasonably ascertained
- The father is not reasonably available
- The pregnancy resulted from rape

7.2.2 The VA Central IRB must verify that the conditions in 7.2.1 above have been met, as well as ensure the following if pregnant women are to be included as potential participants in a research project:

7.2.2.1 If appropriate, prior studies on pregnant animals and non-pregnant women have been conducted, and data for assessing potential risks to the pregnant women and fetuses are provided.

7.2.2.2 That members of the project team or other individuals engaged in the project do not have any part in the following:

- Any decisions as to the timing, method, and procedures used to terminate the pregnancy
- Determining the viability of the fetus at the termination of the pregnancy
- Introducing any procedural changes, for research purposes, into the procedures for terminating the pregnancy.

7.2.2.3 No inducements, monetary or otherwise, are offered to terminate the pregnancy for purposes of the research activity.

7.2.3 The VA Central IRB will make the following determinations for all research involving pregnant women as participants and the results of these determinations will be documented in the meeting minutes:

7.2.3.1 That all of the above requirements have been met.

7.2.3.2 That adequate provision has been made to monitor the risks to the pregnant participant and the fetus.

7.2.3.3 That adequate consideration has been given to the manner in which potential participants are going to be selected, and that adequate provision has been made to monitor the actual informed consent process to include the following:

7.2.3.3.1 Oversight of the actual process by which individual consents are secured either by approving enrollment of each individual into the project by local site compliance officials or by having the local site compliance officials verify through sampling that approved procedures for enrollment of individuals into the project are being followed.

7.2.3.3.2 Monitoring the progress of the research and intervening as necessary, through such steps as having local compliance officials regularly visit the researchers and performing continuing evaluations to determine if any unanticipated risks have arisen.

7.3 Research Involving Prisoners. Research involving prisoners may not be conducted by VA investigators while on official duty, in VA facilities or at VA-approved off-site facilities unless a waiver has been granted by the Chief Research and Development Officer (CRADO). The research proposed must meet one of the permitted research categories specified in 45 CFR 46 Subpart C 46.301 – 46.306(a)(2).

7.3.1 If a project involves prisoners as participants, the investigator will complete VA Central IRB Form 110b, Vulnerable Population Supplement (Prisoners) (Attachment 2) and submit it the VA Central IRB along with the rest of the project documentation.

7.3.2 When the convened IRB reviews research that involves prisoners as participants, one or more individuals who are prisoners or prisoner representatives must be at the convened meeting when the project is reviewed.

7.3.3 The VA Central IRB verifies that the biomedical or behavioral research involving prisoners as participants involves only one or more of the following criteria as specified in 45 CFR 46.306:

7.3.3.1 Study of the possible causes, effects, and process of incarceration and of criminal behavior, provided that the project presents no more than minimal risk and no more than inconvenience to the participants.

7.3.3.2 Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the project presents no more than minimal risk and no more than inconvenience to the participants.

7.3.3.3 Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological issues such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.

7.3.3.4 Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health and well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine and ethics, and published notice, in the Federal Register, of the intention to approve such research.

7.3.4 The VA Central IRB may approve research involving prisoners only if it determines that all of the following criteria are met. The determinations made by the VA Central IRB are documented in the meeting minutes and the VA Central IRB decision document.

7.3.4.1 The research pertains to one of the above permissible categories.

7.3.4.2 Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

7.3.4.3 The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

7.3.4.4 Procedures for the selection of participants in the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners and that control participants are selected randomly from the group of available prisoners who meet the characteristics needed for the particular research unless the investigator provides justification in writing for following some other procedures.

7.3.4.5 The information is presented in a language which is understandable to the participant population.

7.3.4.6 Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.

7.3.4.7 Where there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision is made for such examination or care that takes into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

7.3.5 If an investigator becomes aware of a participant who becomes a prisoner after enrollment, the investigator must notify the VA Central IRB immediately by submitting a written notification to the VA Central IRB Co-Chair either indicating the participant is being withdrawn from the study or requesting that the participant be continued on the project. The Co-Chair may approve the continued participation if it is determined that the continued participation is in the best interest of the participant. If it is determined that the participant should continue in the study, the investigator must complete the VA Central IRB Form 110b and submit it as an amendment to the project, as well as apply to the CRADO for the required waiver.

7.3.6 If the research involving prisoners is supported in part by the Department of Health and Human Services, a copy of the proposal and the VA Central IRB decision documents will be express mailed to the Office of Human Research Protections (OHRP)for review. The research may not proceed until the investigator has been notified that the VA Central IRB, OHRP, and the applicable local site Research and Development (R&D) offices have all approved the research.

7.4 Research Involving Children. Research involving children may not be conducted by VA investigators while on official duty, in VA facilities or at VA-approved off-site facilities unless a waiver has been granted by the Chief Research and Development Officer (CRADO). The VA Central IRB must review and approve the project and certify that it involves no greater than minimal risk prior to a waiver being sought. The VA Central IRB does not review or approve research involving children who are wards as participants.

7.4.1 The VA Central IRB reviews any project that involves children as research participants in accordance with 45 CFR 46, Subpart D and 21 CFR Part 50, Subpart D. Any project that the VA Central IRB determines involves greater than minimal risk to children as participants will not be approved. VA Central IRB determinations are documented in the minutes.

7.4.2 No vulnerable population supplement is required. However, the VA Central IRB will ensure that requirements for permission by parents or guardians and for assent by children are in accordance with Subpart D regulations, and as is determined by state or local law for the jurisdiction in which the research will take place.

7.4.2.1 In determining whether children are capable of assenting, the VA Central IRB shall take into account the ages, maturity and psychological state of the children involved. If the VA Central IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted the assent of the children is not a necessary condition for the approval and conduct of the research. Additionally, even where the VA Central IRB determines that the children are capable of providing assent, it may still waive the assent requirement if **all** of the following conditions are met:

- The waiver of the assent requirement will not adversely affect the rights and welfare of the children
- The research could not practicably be carried out without the waiver
- Whenever appropriate, the children will be provided with additional pertinent information after participation

7.4.2.2 Where the VA Central IRB determines that assent is required, it shall determine whether and how the assent must be documented depending upon the age of the child and the design of the study.

7.4.2.3 The VA Central IRB may determine that the permission of one parent is sufficient for studies described at Subpart D, 46.404 and 46.405. For studies described at 46.406 and 46.407 permission by both parents is required. Permission by parents or guardian will be documented in accordance with VA Central IRB SOP 105, Informed Consent Requirements.

7.4.3 The VA Central IRB closely reviews the site applications for all sites where research with children will be conducted to ensure that the site has appropriate facilities for caring for children.

7.4.4 A VA Central IRB member or ad hoc advisor having appropriate pediatric expertise must be present at the convened meeting of the VA Central IRB when any project involving children as research participants is reviewed.

7.5 Research Involving Participants with Impaired Decision-Making Capacity. In order for the research to be reviewed at a convened VA Central IRB meeting, there must be at least one member in attendance who has experience with the cognitively

impaired and at least one member who has experience in the type of research being reviewed. One member may meet both requirements if qualified. VA Central IRB members are provided training related to specific research populations, such as persons with impaired decision-making capacity.

7.5.1 For all projects involving participants with impaired decision-making capacity, the investigator must complete and submit VA Central IRB Form 110c, Vulnerable Population Supplement (Impaired Decision-Making Capacity) (Enclosure 3) and submit it with the rest of the required project documents.

7.5.2 The VA Central IRB may approve research involving participants with impaired decision-making capacity only if it determines that **all** the following conditions are met. The results of these determinations are documented in the meeting minutes and in the VA Central IRB decision document.

7.5.2.1 Only incompetent persons or persons with impaired decision making capability are suitable as research participants. The investigator is required to justify in the project application that competent persons are not suitable for the research and that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as participants. This category of participants cannot be selected by investigators as potential participants simply because they may be readily available.

7.5.2.2 The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. Incompetent people or persons with impaired decision-making capacity are not to be participants in research that imposes a risk of injury, unless that research is intended to benefit that participant and the probability of benefit is greater than the probability of harm.

7.5.2.3 Procedures describe how and by whom capacity to consent will be assessed in populations where it is likely that capacity is impaired. Procedures describe how participant's representatives will be informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. Health care agents (appointed under Durable Power for Health Care – a DPAHC) and next of kin, or guardians, will be given descriptions of both the proposed research project and the obligations of the participant's representative. They will be told that their obligation is to try and determine what the participant would do if competent, or if the participant's wishes cannot be determined, what they think is in the best interest of the incompetent person.

7.5.2.3.1 Such consent may be requested and accepted only when the prospective research participant is incompetent or has an impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note.

7.5.2.3.2 The determination must be made in accordance with the following requirements:

- The practitioner, in consultation with the chief of service, or COS, may determine after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
- Consultation with a psychiatrist or licensed psychologists must be obtained when the determination that the prospective research subject lacks decision-making capacity is based on a diagnosis of mental illness.
- Disclosures required by VHA handbook 1200.05 to be made to the subject by the investigator must be made to the subject's surrogate
- If feasible, the practitioner must explain the proposed research to the prospective subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study.

7.5.3 If all the above criteria are met, the VA Central IRB may approve the research on the basis of the investigators obtaining informed consent from the participant's legally authorized representatives.

7.5.3.1 The VA only allows certain surrogate entities to provide consent for research purposes. These are a health care agent appointed by the participant in a medical power of attorney or other similar legal document; court-appointed guardian of the person, or the next-of-kin.

7.5.3.2 The next-of-kin may provide consent for research purposes in the following order of priority unless otherwise specified by applicable state law: spouse, adult child (18 years of age or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older.)

7.5.4 For participants with fluctuating or decreasing decision-making capability, the VA Central IRB may require a re-consenting process with surrogate consent. The IRB will give special consideration to continuing review timeframes and may require more frequent review.

7.5.5 The VA Central IRB determines during its review of the project whether an assent process is required. If required, the VA Central IRB determines whether the plan for assent is adequate. Even if the VA Central IRB does not require assent, no participant that does not give assent may be forced or coerced to participate, even if the legally authorized representative consents for the participant. Investigators should also explain the proposed research project to the prospective participant when feasible.

7.6 Research Involving Other Special Classes of Participants. The VA Central IRB considers students, VAMC employees, patients for whom an investigator provides

medical care, the economically and/or educationally disadvantaged; individuals who have limited or no English language proficiency, and the terminally ill, as potentially vulnerable participants since they may be susceptible to undue influence or coercion. The VA Central IRB also evaluates other populations where cultural differences may make them susceptible to undue influence or coercion, such as Native Americans.

7.6.1 There is no additional vulnerable population supplement required by the VA Central IRB for these special classes. The VA Central IRB reviews the potential risks and benefits of each proposed project on a case-by-case basis with increased emphasis on possible safeguards that may need to be implemented to protect the participant's rights and welfare.

7.6.2 The VA Central IRB has the following requirements when some or all of the participants fall into one of these special classes:

7.6.2.1 Students and Employees. When directly solicited to participate in a project, anyone with an employment or academic relationship to the VAMC, will be informed that their participation in the project, or refusal to do so, will in no way influence their employment, ratings, or subsequent recommendations. The involvement of students or employees in the project requires a disclosure in the informed consent form acknowledging that refusal to participate will have no influence on their academic progress or employment status.

7.6.2.2 Illiterate Participants and Literate Participants Who Cannot Sign the Informed Consent Document. If the use of illiterate participants is proposed, or participants who are literate but cannot physically sign the consent document, the investigator will detail how the informed consent is going to be obtained.

7.6.2.2.1 For illiterate participants, at a minimum, the investigator will include in the description that the informed consent document is read to the participant and the document then signed by the participant in the signature section by the participant "making their mark" and how this was done. The VA Central IRB requires both a witness to the mark and the person conducting the consent also sign and date the consent form.

7.6.2.2.2 A similar process is followed for potential participants who are literate and mentally capable of giving informed consent but physically unable to sign the form. The VA Central IRB can add additional stipulations depending upon the capabilities of the study population and the research design.

7.6.2.2.3 The investigator must specify on the Local Site Investigator Application if there are any state and local laws that govern how an illiterate subject is to "make their mark " or how a literate person who cannot physically sign the form, indicates consent if this differs from that approved as part of the PI Application.

7.6.2.3 Non-English Speaking Participants. Most VA research involves Veterans as subjects. Veterans by the nature of their service are deemed to be proficient in English.

7.6.2.3.1 If the involvement of participants who do not speak or read English is proposed (this would mainly involve family members of Veterans), a translator will be present to assist in the consent process and act as witness. A professional translator is preferred. In no case should the translator be a family member of the prospective subject. Consent documents will be written in a language understandable to the participant population and a copy of the translated document forwarded to the VA Central IRB for review prior to enrollment of any participants. The VA Central IRB may use the expedited review procedure in reviewing this document if the English language version has already been approved and the translation is done by a certified translator.

7.6.2.3.2 Other situations will be reviewed on a study by study basis.

7.6.2.4 Investigator is Participant's Medical Provider. For projects in which an investigator also serves as the primary physician for potential participants, someone other than the investigator will be designated to obtain the informed consent. Potential participants must be informed in the consent document that refusal to participate will in no way affect their current or future treatment.

7.6.2.5 Educationally or Economically Disadvantaged Participants. For educationally disadvantaged participants, the VA Central IRB may require investigators to include in the project a method for the participants to demonstrate their understanding of the risks and benefits involved, such as answering questions or filling out a questionnaire to determine if they understood the concepts relayed. For potential participants who are economically disadvantaged, the VA Central IRB will pay particular attention to any payment that may be offered for participation in the project to ensure it is reasonable and of such a nature that it would not be a factor in causing an undue influence on the participant.

7.6.2.6 Terminally Ill Participants. Terminally ill patients may be considered a special class of participants that may be subject to undue influence or coercion based on their lack of alternatives. Investigators will ensure that the nature, magnitude, and probability of the risks and benefits of the research are identified as clearly and as accurately as possible. Accurate information concerning eligibility for participation, treatment options, and risks and benefits will be conveyed clearly and in a manner that will not either engender false hope or eliminate all hope.

7.6.3 Although not considered a vulnerable population or special class of participants in federal regulations, the VA Central IRB may determine that participants require additional protections based on the design of a particular study. If this determination is made, it will be documented in the minutes and the project approval letter.

7.7 Additional Safeguards. After reviewing a project, the VA Central IRB may require additional safeguards to protect the rights and welfare of the participants. Some of these measures may include but are not limited to the following:

7.7.1 Require a reduction in payment or a change in the form of payment given.

7.7.2 Involvement of family members and caregivers in the consent process and/or a requirement for periodic re-consent.

7.7.3 Require third-party consent monitors during the recruitment and consenting process.

7.7.4 Require longer waiting periods between the consent process and signing the consent document.

7.7.5 Repeated consent sessions with groups of participants and/or the use of audiovisual aids.

7.7.6 More frequent continuing review cycles.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

8.3 45 CFR 46, Department of Health and Human Services, Protection of Human Subjects

8.4 VHA Directive 2001-028, Research Involving Children

8.5 Institutional Review Board Guidebook (OHRP)

3 Attachments
1. VA Central IRB Form 110a, Vulnerable Population Supplement (Pregnant Women)
2. VA Central IRB Form 110b, Vulnerable Population Supplement (Prisoners)
3. VA Central IRB Form 110c, Vulnerable Population Supplement (Impaired Decision-Making Capacity)

I have reviewed and approved the content of this SOP.

K. Lynn Cates, MD
Director, PRIDE

Date: 4/2/2010

Vulnerable Population Supplement (Pregnant Women)

VA Central IRB
VA Institutional Review Board for Multisite Studies

This form must be included with all project applications that involve pregnant women as potential participants.

I. Study Identification

Title of Study	
Principal Investigator	

II. Protections and Safeguards Included in the Protocol

The investigator must provide a response for each question or statement below.	**YES**	**NO**	**N/A**
1. Where scientifically appropriate, have preclinical studies including studies on pregnant animals and clinical studies including studies on non-pregnant women, been conducted and do they provide data for assessing potential risks to pregnant women and fetuses? *A description of such studies should be included in the project application.*	☐	☐	☐
All of the following questions or statements must be answered yes if this vulnerable population is being proposed as participants in this research.			
2. The risk to the fetus is not greater than minimal, **or** is any risk to the fetus which is greater than minimal caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?	☐		
3. Is any risk the least possible for achieving the objectives of the research?	☐		
4. There are no inducements included in the research, monetary or otherwise, that will be offered to terminate a pregnancy.	☐		
5. Individuals involved in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.	☐		
6. Individuals engaged in the research will have no part in determining the viability of a neonate.	☐		

If additional protections and safeguards are included in the protocol and are not described above, please detail them below.

III. Informed Consent Requirements

The investigator should check the appropriate boxes below to indicate how informed consent will be obtained.

☐	Consent of the pregnant women or her legally authorized representative will be obtained since the research meets one of the following criteria: *(Check one)* ☐ The research holds out the prospect of direct benefit to the pregnant woman. ☐ The research holds out the prospect of direct benefit to both the pregnant woman and the fetus. ☐ The research holds out no prospect of direct benefit to the pregnant woman or fetus but the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
☐	Consent of the pregnant woman and the father, if readily available, will be obtained as the research holds out the prospect of direct benefit solely for the fetus. There are four criteria for relying on the consent of the mother alone: 1. The purpose of the activity is to meet the health needs of the mother, 2. His identity or whereabouts cannot reasonably be ascertained, 3. He is not reasonably available, or 4. The pregnancy resulted from rape.

IV. Investigator Certification

The principal investigator must check each box and sign and date the form.

☐	I understand my responsibilities to follow all applicable VA And federal requirements to protect the rights and welfare of this vulnerable population.
☐	I understand that the informed consent requirements described in VHA Handbook 1200.05 concerning this vulnerable population are not intended to preempt any applicable federal, state, or local laws that require additional information be disclosed for the informed consent to be legally effective.
☐	I agree to follow all additional protections and safeguards for this vulnerable population as described in this project and as required by the VA Central IRB and I will ensure my project team is informed of these protections, safeguards, and requirements.

_____ _____

Signed Date

Vulnerable Population Supplement (Prisoners)

VA Central IRB
VA Institutional Review Board for Multisite Studies

This form must be included with all project applications that involve prisoners as potential participants.

I. Study Identification

Title of Study	
Principal Investigator	

II. Protections and Safeguards Included in the Project

The investigator must provide a response for each question or statement below. All responses must be answered as "Yes" or "N/A" if this vulnerable population is to be included as participants in the project.	YES	NO	N/A
1. Are there any possible advantages to the prisoner from his/her participation in the research when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison that would impair the participant's ability to weigh the risks of the research against the value of such advantages?	☐	☐	☐
2. Are the risks involved in the research commensurate with the risks that would be accepted by non-prisoner volunteers?	☐	☐	☐
3. Are procedures for selection of participants within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities and are these procedures described in the project?	☐	☐	☐
4. If control groups are going to be used, will the control participants be randomly selected?	☐	☐	☐
5. Is the information presented in a language understandable to the general prison population?	☐	☐	☐
6. Does the informed consent document clearly state that participation in the research will not affect parole decisions and has the investigator trained prison authorities in this requirement?	☐	☐	☐
7. If there is a need for follow-up examinations or care of participants after the end of their participation in the research, has adequate provision been made for such examinations or care considering the length of the individual prisoner sentences and are these provisions described in the protocol?	☐	☐	☐

If additional protections and safeguards are included in the project and are not described above, please detail them below.

III. Category of Permissible Prisoner Research

The investigator should check the appropriate box below to indicate the category of permissible prisoner research to which the study pertains

☐	The research is minimal risk and no more than an inconvenience to the participants. It involves the possible causes, effects, and processes of incarceration and of criminal behavior.
☐	The research is minimal risk and no more than an inconvenience to the participants. It involves a study of prisons as institutional structures or of prisoners as incarcerated persons.
☐	The research is a study on conditions particularly affecting prisoners as a class, i.e., social and psychological problems such as alcoholism and drug addiction.
☐	The research is a study on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health and/or well being of the participants.
☐	This is an epidemiologic study. The sole purpose of the project is to describe the prevalence or incidence of a disease or condition by identifying all cases or to study the potential risk factors associated with a disease or condition. The research presents no more than minimal risk and no more than an inconvenience to the participants. Prisoners are not a particular focus of the research.
☐	The research involves a project participant that became incarcerated after enrollment in the Project. It is to the benefit of the project participant to remain enrolled in the project. If yes, please justify:

IV. Investigator Certification

The principal investigator must check each box and sign and date the form.

☐	I understand my responsibilities to follow all applicable VA and federal requirements to protect the rights and welfare of this vulnerable population.
☐	I will ensure all the project team members are trained in the additional protections and safeguards that are to be afforded this vulnerable population as stipulated in this supplement and as may be further mandated by the VA Central IRB.
☐	I understand that I must receive a waiver from the Chief Research and Development Officer per VHA Handbook 1200.05 for conducting research with prisoners as participants after I have obtained approval from the VA Central IRB and the local R&D committees prior to beginning any research on prisoner participants. The only exception is if the VA Central IRB Co-Chair approves the continued participation of a participant who becomes a prisoner after enrollment in a project if it is determined to be in the best interests of the participant until the VA Central IRB had made a decision on the amendment.

_____ _____

Signed Date

Vulnerable Population Supplement (Individuals with Impaired Decision-Making Capacity)

VA Central IRB
VA Institutional Review Board for Multisite Studies

This form must be included with all project submissions that involve individuals with impaired decision-making capacity as potential participants.

I. Study Identification

Title of Study	
Principal Investigator	

II. Protections and Safeguards Included in the Project

Please provide a response for each question or statement below.	YES	NO	N/A
1. Does the protocol give a compelling reason why persons with impaired decision-making capacity are necessary to answer the research question?	☐	☐	☐
2. Does the project expose this vulnerable population to significant risks (including tangible and intangible?)	☐	☐	☐
3. If the project is greater than minimal risk, is there at least a greater probability of direct benefit than risk to the participant?	☐	☐	☐
4. If the project proposes the use of institutionalized individuals does it include an adequate justification for their use?	☐	☐	☐
5. Are there procedures detailed in the project for evaluating the mental status of prospective participants to determine whether they are capable of giving informed consent or assent?	☐	☐	☐
6. Does the research project include a description of the informed consent process for those who lack capacity to consent, including reference to state laws that determine who has authority to consent on behalf of the subject?	☐	☐	☐
7. If a legally authorized representative gives informed consent, will the subject be asked for assent?	☐	☐	☐
8. If a legally authorized representative gives informed consent and assent of the subject is not sought, is the justification for not getting assent detailed in the project?	☐	☐	☐
9. If there is a potential to enroll participants who have temporary or fluctuating decision-making capability, is there a process detailed in the project describing the requirement for re-consent?	☐	☐	☐
10. Have procedures been included in the project detailing procedures to ensure participant's representatives are well informed regarding their roles and obligations to protect participants with impaired decision-making?	☐	☐	☐

If additional protections and safeguards are included in the project and are not described above, please detail them below.

IV. Investigator Certification

The principal investigator must check each box and sign and date the form.

☐	I understand my responsibilities to follow all applicable VA and federal requirements to protect the rights and welfare of this vulnerable population
☐	I understand that the informed consent requirements described in VHA Handbook 1200.05 concerning this vulnerable population are not intended to preempt any applicable federal, state, or local laws that require additional information be disclosed for the informed consent to be legally effective.
☐	I understand VHA Handbook 1200.05 describes the entities allowed to provide surrogate consent for research purposes unless otherwise specified by applicable state law.
☐	I agree to follow all additional protections and safeguards for this vulnerable population as described in this project and as required by the VA Central IRB and I will ensure my project team is informed of these protections, safeguards, and requirements.

_____ _____

Signed Date